

## CLAIMS

1. A mask assembly for a patient comprising:  
a frame having a lateral flange portion with at least a first hole  
therethrough;  
a cushion having a lateral flange portion with at least a second hole  
therethrough; and  
a cushion clip having a lateral flange with at least one rod that passes  
through the first and second holes, the rod having a distal end that is secured to the frame  
when the rod passes through the first and second holes, to thereby sandwich the cushion  
flange between the flanges of the frame and the cushion clip.
2. A mask assembly according to claim 1, wherein the distal end of the rod  
includes an enlarged head portion which forms a one-way snap with the frame.
3. A mask assembly according to any one of claims 1-2, wherein the frame  
flange includes at least one bead intended to form a seal with the flange of the cushion  
upon assembly of the frame, cushion and cushion clip.
4. A mask assembly according to any one of claims 1-3, wherein the frame  
includes an upstanding wall member which provides a support for at least a portion of  
side walls of the cushion.
5. A mask assembly according to any one of claims 1-4, wherein the frame  
includes lateral outriggers each including at least one leg provided to the frame and a  
receptacle configured to receive a respective headgear strap portion.
6. A mask assembly according to claim 5, wherein each said leg is made of a  
resilient, flexible material which allows the outriggers to move towards and away from

the patient for self-tensioning of each headgear strap portion upon donning of the mask assembly by the patient.

7. A mask assembly according to any one of claims 1-6, further comprising a usage indicator provided to at least one of the frame, cushion and cushion clip.

8. A mask assembly according to claim 7, wherein the usage indicator comprises a flexible leg provided to the frame, said flexible leg being subject to stress whitening through repeated bending.

9. A mask assembly according to claim 8, wherein the leg is made of one of polypropylene and polyethylene.

10. A mask assembly according to any one of claims 8-9, wherein the stress whitening is in the form of a warning message visible upon approaching end of life.

11. A mask assembly according to any one of claims 7-10, wherein the usage indicator is activated after no more than 14 days of usage.

12. A mask assembly according to claim 11, wherein the usage indicator is activated after no more than 7 days of usage.

13. A mask assembly according to any one of claims 1-12, wherein the frame comprises flexible, thin wall portions having a thickness of between about 0.25 mm and 1.0 mm.

14. A mask assembly according to any one of claims 1-13, further comprising a port provided in the frame, and a port cap provided in one piece with the cushion.

15. A mask assembly according to claim 14, wherein the frame includes a notch to receive a bridge of the port cap.
16. A mask assembly according to any one of claims 14-15, wherein the port cap includes enlarged lateral wing portions.
17. A mask assembly according to any one of claims 1-16, further comprising an elbow assembly provided to a front face of the frame.
18. A mask assembly according to claim 17, wherein the elbow assembly includes at least one tab member provided to an undercut of the frame.
19. A mask assembly according to claim 18, wherein the tab member and the undercut form a one-way snap connection between the elbow assembly and the frame.
20. A mask assembly according to any one of claims 17-19, wherein the elbow assembly includes an anti-asphyxia valve member.
21. A mask assembly according to any one of claims 17-20, wherein the elbow assembly includes a dome-shape portion with an internal cylindrical tube.
22. A mask assembly according to claim 21, wherein the anti-asphyxia valve member includes a generally cylindrical aperture defining an inner shoulder that frictionally engages the cylindrical tube, and an outer ring portion which engages an upstanding wall member of the dome portion.
23. A mask assembly according to any one of claims 21-22, wherein the dome portion includes at least one vent.

24. A mask assembly according to claim 23, wherein the at least one vent includes a duck bill valve provided thereto.

25. A mask assembly according to any one of claims 22-24, wherein the outer ring portion of the anti-asphyxia valve member includes a shoulder which engages with an edge portion of the upstanding wall member.

26. A mask assembly according to any one of claims 20-25, wherein the anti-asphyxia valve member comprises an elastomeric material.

27. A mask assembly according to any one of claims 1-26, further comprising headgear to support the mask assembly on the patient in use.

28. A mask assembly according to claim 27, wherein the frame includes receptacles to receive respective headgear clips secured to straps of the headgear.

29. A mask assembly according to claim 28, wherein the receptacles include opposed first and second arms provided as part of the frame.

30. A mask assembly according to claim 29, wherein each headgear clip includes first and second arms which engage with the first and second opposed arms of the receptacle when the headgear clip is inserted into the receptacle.

31. A mask assembly according to any one of claims 27-30, further comprising at least one headgear connection portion including a first slot into which an end of the headgear strap is threaded, and a second slot in communication with a gap by which the headgear can be inserted into the second slot.

32. A mask assembly according to any one of claims 27-31, wherein the headgear includes a substantially planar material which includes at least one slit, wherein

the slit may be expanded upon use to define an open area bordered on all sides by at least a portion of the material.

33. A mask assembly according to claim 32, wherein the slit includes a plurality of slits which expand in use to form a net around the occiput of the patient's head.

34. A mask assembly according to any one of claims 32-33, wherein each of the open areas includes a polygon such as a diamond shape and/or a triangle shape.

35. A mask assembly according to any one of claims 32-34, wherein the material is susceptible to accumulation of grime or oils, thereby providing a usage indicator which cannot be cleaned.

36. A mask assembly according to any one of claims 27-35, wherein the headgear includes at least three points of attachment to the frame.

37. A mask assembly according to any one of claims 1-36, wherein the mask assembly is a disposable mask assembly.

38. A mask assembly according to any one of claims 1-37, wherein the mask assembly is a full-face mask assembly.

39. A mask assembly according to any one of claims 1-38, wherein the mask assembly is a nasal mask assembly.

40. A mask assembly comprising:  
a frame,  
a cushion; and  
headgear,  
wherein at least one of the frame, cushion and headgear includes a usage indicator  
as to condition of the mask assembly.

41. A mask assembly according to claim 40, wherein at least a portion of the  
frame is made of a material that exhibits stress whitening after repeated movement.

42. A mask assembly according to claim 41, wherein the stress whitening  
takes the form of a warning signal.

43. A mask assembly according to claim 42, wherein the warning signal is in  
the form of one or more words.

44. A mask assembly according to any one of claims 40-43, wherein the usage  
indicator provides an indication of over usage after no more than 14 days of usage.

45. A mask assembly according to claim 42, wherein the usage indicator is  
exhibited after no more than 7 days of usage.

46. A mask assembly comprising:  
a frame;  
a cushion provided to the frame;  
a cushion clip provided to secure the cushion between the cushion clip and the  
frame via a first connection; and  
a swivel elbow provided to the frame via a second connection,  
wherein at least one of the first and second connections is provided via a one-way  
snap which will deform and/or break upon attempt to disassemble.

47. A mask assembly according to claim 46, wherein the first connection includes a rod provided to the cushion clip which passes through at least one of the cushion and the frame, wherein the rod includes an enlarged head portion which allows assembly of the cushion clip to the frame, but substantially prevents removal of the cushion clip from the frame.

48. A mask assembly according to any one of claims 46-47, wherein the second connection comprises an undercut provided on the frame and at least one tab member provided on a portion of the swivel elbow.

49. Headgear for use with a respiratory mask assembly, comprising:  
a substantially planar piece of material which includes at least one slit before use,  
wherein the at least one slit is expandable to form a substantially enlarged open area in use, so that the material substantially surrounds an occiput of the patient's head.

50. Headgear for use with a respiratory mask assembly according to claim 49, wherein each said open area has a polygon shape, such as a diamond or triangle.

51. Headgear for use with a respiratory mask assembly according to any one of claims 49-50, further comprising a first portion including a first strap portion for connection with a central top portion of a mask assembly, and a second portion including second and third strap portions for connection with lateral sides of the mask assembly.

52. Headgear for use with a respiratory mask assembly according to any one of claims 49-51, wherein the headgear forms a waffle-like pattern in use when worn by the patient.

53. A method of making headgear comprising:  
providing a single piece of material;

creating a plurality slits in the material;  
orienting the slits such that placement of the headgear on a patient's head expands the plurality of slits to form a plurality of open areas spread over the patient's head in use, wherein the material includes at least first and second strap end portions adapted for connection to a mask assembly.

54. A method of making headgear according to claim 53, wherein the open areas are in the form of polygons which are bordered on all sides by a portion of said material.

55. A method of making headgear according to claim 54, wherein the polygons include triangles or diamonds.

56. A method of making headgear according to any one of claims 53-55, wherein each of the strap end portions is formed in part by one of said plurality of slits.

57. A method of making headgear according to any one of claims 53-56, wherein the headgear includes at least three strap end portions.

58. A mask assembly comprising:  
a frame;  
an elbow provided to the frame and including an inlet conduit; and  
a valve member provided between the frame and the elbow, the valve member being configured to allow breathing of ambient air and to prevent back flow of gas towards the inlet conduit of the elbow in an unpressurized state.

59. A mask assembly according to claim 58, wherein the elbow includes an internal cylindrical tube in communication with atmosphere and a dome that supports the tube, and



wherein any back flow is guided through the tube and not the inlet conduit in the unpressurized state.

60. A mask assembly according to any one of claims 58-59, wherein the elbow includes at least one inlet slot structured to allow ambient air to be channeled between the valve member and the frame for supply to the patient, when operating in the unpressurized state.

61. A mask assembly according to any one of claims 59-60, wherein the valve member is structured to separate from the tube during operation in a pressurized state, to thereby allow pressurized gas to enter an aperture of the frame.

62. A mask assembly according to any one of claims 58-61, wherein the valve member creates an audible indicator during operation in a pressurized state.

63. A mask assembly according to claim 62, wherein the valve member creates the audible indicator upon proper assembly.

64. A mask assembly according to claim 62, wherein the valve member creates the audible indicator upon improper assembly.

65. A mask assembly according to claim 58, wherein the elbow includes a center tube portion and an inner tube suspended from a dome portion of the elbow.

66. A mask assembly according to claim 65, wherein the inner tube communicates with the atmosphere via a profiled end that is smaller towards atmosphere.

67. A mask assembly according to any one of claims 65-66, wherein the center tube portion includes an aperture near its connection to the dome portion and is generally aligned with the inlet conduit.